

OCT 18 2005

See attached form for additional information.

Interagency Report Control No. *qan*

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 14-R-0138

FORM APPROVED
OMB NO. 0579-0036

CUSTOMER NUMBER: 1664

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Beth Israel Deaconess Medical Center
330 Brookline Avenue
Boston, MA 02215

Telephone: (617) -667-4922

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquiliz- ing drugs would have adversely affected the procedures, res- ults or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report)	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	9	0	9
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	12	0	12
7. Hamsters	0	0	0	232	232
8. Rabbits	0	37	60	0	97
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	29	0	29
11. Pigs	0	27	148	0	175
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

Print)

DATE SIGNED

(b)(6), (b)(7)c

10-6-05

RGW

Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 14-R-0138
2. Number 232 of animals used in this study.
3. Species (common name) hamsters of animals used in this study.
4. Explain the procedure producing pain and/or distress.
Syrian Golden Hamsters weighing 100-200 gm will be given a single injection of clindamycin (1-5mg) and will then be allowed to become passively infected with *Clostridium difficile* from the environment.
5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)
Clostridium difficile administration following clindamycin injection (a nosocomial infection mimicking model) is used to induce an inflammatory reaction in the cecum. It is thus expected that animals will experience a certain level of discomfort. However, we do not plan to provide animals with antispasmodic drugs because this may inhibit the clearance of the organism from the intestine and may worsen the colitis (George et al., Gastroenterology 79:366, 1980; Pothoulakis and LaMont, Gastroenterology Clinics of North America, 22:623-627, 1993). In addition, we do not plan to use other form of pain relief since it may affect the responses we measure (e.g. degree of inflammation and diarrhea). However, animals will be monitored three times/daily and may any sign of severe distress (extended periods (6 days) of weight loss progressing to an emaciated state, anorexia for 24-48 hours, prolonged lethargy (> 3 days), signs of paralysis, skin erosions or trauma, hunched posture, distended abdomen) be observed, the animals will be immediately euthanized. (Pothoulakis - 085-2003)
6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency _____ CFR _____

The Animal Facilities at Beth Israel Deaconess Medical Center are located at the following addresses:

(b)(2)High, (b)(7)f